K091452

AUG 21 2009


# 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

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| **Submitter:** | CAS Medical Systems, Inc. |
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| **Prepared:** | May 15, 2009 |
| **Trade Name:** | FORE-SIGHT® Cerebral Oximeter Monitor |
| **Common Name:** | Model MC-2000 Series |
| **Classification Name:** | Cerebral Oximeter (870.2700) |

**EQUIVALENCE (Predicate Device)**

The FORE-SIGHT® Cerebral Oximeter Monitor, Model MC-2000 is equivalent to the following devices:

- CAS Adult Cerebral Oximeter Model 2000 (K061960 / K073036 / K083892)
- Somanetics INVOS® 5100C / 3100A Cerebral Oximeter (K001842 / K960614 / K051274 / K080769 / K082327);
- Spectros T-Stat™ 303 Microvascular Tissue Oximeter (K040684);

**DESCRIPTION**

The Cerebral Oximeter Monitor measures cerebral tissue oxygen saturation allowing the clinician to accurately determine absolute levels of brain tissue blood oxygen saturation and brain venous oxygen saturation in the brain. This measurement can be of significant value in numerous acute care (OR, ICU, ER) situations, providing health care professionals with information to guard against neurological injuries due to compromised brain oxygenation, which can occur during many surgical and clinical procedures.

The Cerebral Oximeter Monitor consists of an optical transducer containing a laser light source and photodiode detectors, and a graphic display monitor with user interface. The non-invasive, reflection mode, optical transducer is placed on the forehead of the subject via a disposable sensor attachment to determine cerebral oxygenation. The Cerebral Oximeter Monitor is safe to use, because it is designed to operate as a Class I laser product, the safest FDA laser classification. Additional safety features include a laser interlock system designed to prevent laser operation in case the optical transducer is not securely attached to the subject. A patent-protected algorithm optimizes accuracy of the device for measurements of absolute cerebral tissue oxygen saturation..

**Cerebral Oximeter Monitor Intended Use**

The FORE-SIGHT® Cerebral Oximeter, Model MC-2000 Series is indicated for the continuous noninvasive monitoring of regional hemoglobin oxygen saturation of blood in the brain (SctO2). It is intended for use in any individual at risk for reduced-flow or no-flow ischemic states.

When used with FORE-SIGHT large sensors, the FORE-SIGHT MC-2000 Cerebral Oximeter Monitor is indicated for use with adults and children over 40Kg. When used with the FORE-SIGHT medium sensors, the FORE-SIGHT MC-2000 Cerebral Oximeter is indicated for use with small adults and children between 4 kg and 80 kg. When used with FORE-SIGHT small sensors the FORE-SIGHT MC-2000 Series Cerebral Oximeter Monitor is indicated for infants and neonates $\leq$ 8Kg.

## Cerebral Oximeter Monitor Technology Compared to Predicate Devices

The FORE-SIGHT Cerebral Oximeter Monitor compares substantially to one or more of the cited predicate devices in that they use fundamentally the same optical operating principle, called diffuse reflectance spectroscopy. All cited monitors use light to probe a cross-section tissue microvasculature. (mixed bed of arterioles, capillaries and venules). The Cerebral Oximeter Monitor and predicate devices analyze light returning from tissue, after having passed through tissues, for hemoglobin in its oxygenated and deoxygenated forms in the optically sampled region. All cited monitors calculate oxygen saturation. This value reflects the percentage of oxygenated hemoglobin in the sampled tissue.

## Non-Clinical Performance Testing to Demonstrate Substantial Equivalence

The Cerebral Oximeter Monitor has been tested to the following standards in accordance with CAS Medical Systems Product Performance Specifications. The following non-clinical tests have been performed:

- UL 60601-1 Safety testing for use of the UL Classified mark;
- CAN/CSA C22.2 No. 601.1-M90
- IEC 60601-1 Safety of Medical Electrical Equipment;
- EN 60601-1 Safety of Medical Electrical Equipment;
- IEC 60601-1-1 Safety of Medical Electrical Systems;
- IEC 60601-1-2: 2001 Safety of Medical Electrical Equipment with regard to EMC Emissions and EMC Immunity;
- IEC 60601-1-4 Safety of Programmable Electrical Medical Systems;
- IEC 60601-1-8 Safety of Alarm Systems for Medical Equipment/Systems;
- IEC 60825-1: Safety of Laser Products (with amendments A1 and A2);

In addition to the above laboratory tests, CAS has conducted a full compliment of individual hardware, software and systems monitor and sensor verification and validation studies.

## Clinical Testing to Show Substantial Equivalence

**Adult Subject Validation:** Clinical data on adult subjects was collected at the Duke University Medical Center in Durham, North Carolina. In this study, healthy adult volunteers were subjects for comparison using an internal jugular bulb catheter on the subject's right side and a radial arterial line on the left. Two sensors from the FORE-SIGHT Cerebral Oximeter Monitor were placed bilaterally on the patient's forehead. Hypoxic mixtures of gas were delivered and data was collected in 5 minute intervals during periods of ascending and descending concentrations. At each data collection point, blood samples were drawn simultaneously from the jugular bulb and the radial arterial catheters and analyzed for hemoglobin oxygen saturation using a co-oximeter. The patient was monitored and the protocol stopped if $SpO_2$ values from a pulse oximeter reached 70%.

**Infant & Neonate Subject Validation:** 2044 hours of clinical data was collected at the Children's National Medical Center in Washington, DC, and the Children's Hospital of Atlanta (CHOA), Emory University, Atlanta, GA, from subjects undergoing veno-venous Extracorporeal Membrane Oxygenation (VV-ECMO) with cephalad catheterization. In this study, cerebral venous oxygen saturation ($SjvO_2$) measured from blood samples obtained from the internal jugular vein via the cephalad catheter, along with pulse oximetry arterial oxygen saturation ($SaO_2$) data, were recorded from VV-ECMO neonates without alteration to patient care or blood oxygenation levels while being monitored by the FORE-SIGHT Cerebral Oximeter Monitor over a period of several days for each subject.

**Pediatric Subject Validation:** Clinical data on pediatric subjects were collected at Boston Children's Hospital in Boston, MA from subjects undergoing cardiac catheterization. In this study, cerebral venous oxygen saturation ($SjvO_2$) measured from blood samples obtained from the internal jugular vein, along with arterial oxygen saturation ($SaO_2$) data, were recorded from cardiac catheterization subjects without alteration to patient care while being monitored by the FORE-SIGHT Cerebral Oximeter Monitor

## Conclusions Drawn from Clinical and Non-Clinical Testing

The data is presented as Precision measured as one standard deviation for the cerebral tissue oxygen saturation (SctO2) parameter to determine the accuracy of the monitor.

**Adult $SctO_2$:** Using the FORE-SIGHT Large sensor, the Cerebral Oximeter $SctO_2$ showed a strong correlation with the reference $SctO_2$ over the spectrum of values between 45 to 95%. The Precision (1 Standard deviation) for the Cerebral Oximeter Monitor $SctO_2$ compared to reference $SctO_2$ derived from co-oximetry of arterial ($SaO_2$) and jugular bulb ($SjvO_2$) blood samples was ± 3.7 %, based on Equation 1 below.

**Pediatric $SctO_2$:** Using the FORE-SIGHT Medium sensor, the Cerebral Oximeter $SctO_2$ showed a strong correlation with the reference $SctO_2$ over the spectrum of values between 50 to 99%. The Precision (1 Standard deviation) for the Cerebral Oximeter Monitor $SctO_2$ compared to reference $SctO_2$ derived from co-oximetry of arterial ($SaO_2$) and jugular bulb ($SjvO_2$) blood samples was ± 4.86 %, based on Equation 1 below.

**Infant & Neonate $SctO_2$:** Using the FORE-SIGHT Small sensor, the Cerebral Oximeter $SctO_2$ showed strong agreement with the reference $SctO_2$ over the spectrum of values between 50 to 99%. The Precision (1 Standard deviation) for the Cerebral Oximeter Monitor $SctO_2$ compared to the reference $SctO_2$ derived from pulse oximetry measured arterial oxygen saturation $SaO_2$ and co-oximetry measured internal jugular vein venous oxygen saturation ($SjvO_2$) from blood samples was ± 5.0 %, based on Equation 1.

$$Reference\ SctO_2\% = SaO_2 \times 0.3 + SjvO_2 \times 0.7 \qquad Equation\ 1$$

The Cerebral Oximeter Monitor $SctO_2$ value represents oxygen saturation in the brain tissue microvasculature containing venous and arterial blood volume at a ratio of 70:30.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

AUG 21 2009

CAS Medical Systems, Inc.
c/o Ron Jeffrey
Director of Regulatory Affairs
44 East Industrial Rd.
Branford, Connecticut 06405

Re: K091452
Trade/Device Name: Fore-Sight, Model MC-2000 SERIES
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: MUD
Dated: July 29, 2009
Received: July 30, 2009

Dear Mr. Jeffrey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Kezia Alexander for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## Indications for Use

510(k) Number: K091452

Device Name: FORE-SIGHT™ Cerebral Oximeter Monitor, Model 2000 Series.

Indications for Use:

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Prescription Use _✔__ AND/OR Over-the-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

M L B Nichols

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K091452